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(71) Applicant (<i>for all designated States except US</i>): NOVARTIS NUTRITION AG [CH/CH]; Monbijoustrasse 118, CH-3001 Bern (CH).		(72) Inventors; and (75) Inventors/Applicants (<i>for US only</i>): LUSTENBERGER, Alice [CH/CH]; Murtenstrasse 226, CH-3207 Bern (CH). CLAYTON, Diane, Elizabeth [GB/CH]; Au Charmin, CH-1648 Hauteville (CH).	
(74) Agent: SMOLDERS, Walter, Novartis AG, Corporate Intellectual Property, Patent & Trademark Dept., CH-4002 Basel (CH).		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(54) Title: NUTRITIONAL SUPPLEMENT FOR PREGNANT AND LACTATING WOMEN			
(57) Abstract			
<p>A nutritional composition for pregnant and lactating women comprising: a non-milk-derived protein source, a dietary fibre and/or fibre-like substance, a source of polyunsaturated fatty acids, minerals and vitamins recommended for pregnant and lactating women, characterized in that the composition is lactose free and contains less than 2 % of milk or milk-derived products by weight of dry components of the composition.</p>			

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Nutritional Supplement for Pregnant and Lactating Women

This invention provides a nutritional composition for pregnant and lactating women and food products or dietary supplements comprising said composition.

During pregnancy and lactation a woman's diet has to provide sufficient nutrients both for the maintenance of her own body and the growth of the foetus in her womb and/or the nursing baby. The diet during such periods should be very well balanced and cover the needs of all essential nutrients. When the extra-needs of essential nutrients are compared with the extra-needs of energy during the pregnancy and lactation, it can be seen that the needs of essential nutrients increase by 50% or more whereas the energy needs increase only 15-25%. Therefore, if the diet of the pregnant and lactating women does not change in quality the extra-needs of essential nutrients might not be covered. Administering a specifically tailored "nutrient dense" nutritional composition helps ensure that the extra-needs of essential nutrients during pregnancy and lactation are covered.

Constipation is common in pregnancy. This is thought to be related to the increase in circulating progesterone and possibly decreased levels of motilin. Dietary fibre has a major effect on colonic function and is a safe means to relieve pregnant women of their constipation.

The important role of essential fatty acids in neural development of the foetus and young infant is becoming clearer and because disorders of brain development can be permanent, proper provision should be made to protect the long chain polyunsaturated fatty acid status of both term and preterm infants to ensure optimum conditions for the development of membrane-rich systems such as the brain, nervous, and vascular system. Adequate levels of long chain polyunsaturated fatty acids in the maternal diet even shortly before and during pregnancy and during lactation are, therefore, important to avoid nutritional inadequacies of the foetus and nursing baby.

Calcium is among the nutrients the recommended levels of which is increased proportionately more than that of energy and the other nutrients during pregnancy and lactation and taking extra milk or dairy products will normally provide additional calcium.

This recommendation cannot be followed by all women. In particular lactose intolerant individuals need an alternative calcium source which contains no lactose. Lactose-intolerance is one of the major reasons for milk intolerance. Furthermore, it is known that exposure of the foetus via the placenta to cow's milk can result in primary sensitisation to cow's milk allergens, leading to positive proliferative responses when the infant is exposed to cow's milk after birth.

It is an object of the present invention to provide a nutritional composition which supplies the extra-needs of essential nutrients for pregnant and lactating women and which is lactose-free and which is essentially free of milk products and is, therefore, suitable for women who are lactose intolerant and women expecting a baby with an increased risk of developing cow's milk allergy because of i.a. a family history of allergies.

The present invention, therefore, provides a nutritional composition for pregnant and lactating women comprising:

a non-milk-derived protein source,
a dietary fibre and/or fibre-like substance,
a source of polyunsaturated fatty acids,
minerals and vitamins recommended for pregnant and lactating women,
characterized in that the composition is lactose-free and contains less than 2 % of milk or milk-derived products by weight of dry components of the composition.

Preferably the composition according to the invention contains less than 1.5 weight % (more preferred less than 1 weight%) by weight of dry components of the composition of milk or milk-derived products such as caseinates, particularly preferred the composition is milk-free, i.e. it contains no detectable levels of milk or milk-derived products. Lactose-free as used herein means that the composition contains no detectable lactose.

Preferably the composition according to the invention comprises the following minerals and vitamins recommended for pregnant and lactating women: calcium, magnesium, iron, copper, zinc, iodine, vitamin A, vitamin E, vitamin B₁, vitamin B₂, vitamin B₆, vitamin B₁₂, vitamin C, folic acid, niacin.

The composition of the invention preferably comprises the following daily amounts of essential nutrients:

- 1.0 mg (preferably 1.0 g) to 50 g of a non-milk-derived protein source, preferably 8 to 15 g, particularly preferred 10 g,
- 1.0 mg to 30 g of dietary fibre and/or fibre-like substance, preferably 4 to 6 g, particularly preferred 5 g,
- of polyunsaturated fatty acids
- 0.01 µg (preferably 0.1 µg) to 2.0 g of long-chain polyunsaturated fatty acids, preferably 0.1 to 0.4 g, particularly preferred 0.25 g and/or
 - 0.5 g to 12 g of alpha-linolenic acid, preferably 0.5 to 2.0 g, particularly preferred 1.0 g and/ or
 - 1 g to 30 g of linoleic acid, preferably 2.0 to 5.0 g, particularly preferred 3.0 g,
0.1 mg to 3.6 g calcium, preferably 320 to 530 mg, particularly preferred 400 mg,
0.1 mg to 1.1 g magnesium, preferably 60 to 90 mg, particularly preferred 75 mg,
0.01 mg to 90 mg iron, preferably 8 to 12 mg, particularly preferred 10 mg,
0.01 mg to 60 mg zinc, preferably 4 to 6 mg, particularly preferred 5 mg,
0.01 mg to 3 mg copper, preferably 0.1 to 0.4 mg, particularly preferred 0.25 mg,
0.01 mg to 0.6 mg iodine, preferably 24 to 36 µg, particularly preferred 30 µg,
0.01 mg to 4.0 mg vitamin A, preferably 80 to 120 µg, particularly preferred 100 µg,
0.01 mg to 40 mg vitamin E, preferably 2.4 to 3.6 mg, particularly preferred 3 mg,
0.01 mg to 5 mg vitamin B₁, preferably 0.16 to 0.24 mg, particularly preferred 0.2 mg,
0.01 mg to 6 mg vitamin B₂, preferably 0.32 to 0.48 mg, particularly preferred 0.4 mg,
0.01 mg to 7 mg vitamin B₆, preferably 0.24 to 0.36 mg, particularly preferred 0.3 mg,
0.01 µg to 8 µg vitamin B₁₂, preferably 0.4 µg to 0.6 µg, particularly preferred 0.5 µg,
0.01 mg to 300 mg vitamin C, preferably 20 to 30 mg, particularly preferred 25 mg,
1.0 µg to 1.2 mg folic acid, preferably 160 to 240 µg, particularly preferred 200 µg,
and
0.01 mg to 60 mg niacin, preferably 1.6 to 2.4 mg, particularly preferred 2 mg.

The following sources are suitable as non-milk-derived protein source: egg protein, soy protein (particularly soy protein low in isoflavones), soy isolate, pea protein, pea hydrolysate, rice protein, rice hydrolysate, soy hydrolysate, wheat hydrolysate, potato

hydrolysate, rapeseed protein, lupin protein, wheat protein and/or wheat isolate. Preferably the non-milk-derived protein source is soy protein.

Suitable dietary fibres include insoluble and soluble fibres and mixtures thereof. Suitable insoluble fibres include one or more members selected from the following group: cellulose, wheat fibre, soy fibre, pea fibre, oat fibre and beet fibre. Suitable soluble fibres include one or more members selected from the following group: pectin, xanthan gum, hydrolysed guar gum and gum arabic. Suitable substances with fibre-like activity are inulin and oligosaccharides such as hydrolysed inulin, soy- oligosaccharides, galacto-oligosaccharides, fructo-oligosaccharides and xylo-oligosaccharides. Oligosaccharides are prebiotic substances with fibre-like physiological activity, i.e. they have mild laxative effect. Preferably the composition comprises oligosaccharides and in particular fructo-oligosaccharides and/or xylo-oligosaccharides as fibre-like substances.

For mixtures of soluble fibers and/or fibre-like substances with insoluble fibers the weight ratios are as follows:

a) soluble and/or fiber-like substance to insoluble fiber can vary from 9:1 to 2:3, a preferred weight ratio is about 2-4 part soluble fibers and/or fibre-like substance to about 1 part insoluble fibers.

Suitable polyunsaturated fatty acids (PUFAs) include the long-chain PUFAs (from C20 upwards) such as docosahexaenoic acid (DHA), docosapentaenoic acid (DPA), eicosapentaenoic acid (EPA), arachidonic acid (AA), or their precursors alpha-linolenic acid, linoleic acid and/or docosatetraenoic acid (DTA= Adrenic), whereby the long-chain PUFAs DHA and/or EPA are preferred. Preferred sources of long chain polyunsaturated fatty acids are fish oil which typically contains 15 to 25% DHA and 5 to 15% EPA as well as sources from microalgae which typically contain 40% DHA. If the long-chain polyunsaturated fatty acid employed is of the precursor-type which still has to be metabolized to the active form in the body such as alpha-linolenic acid or linoleic acid, then the daily amount preferably lies in the range of 0.5 g to 12 g or 1 g to 30 g respectively. If the long-chain polyunsaturated fatty acid is already in the active form such as DHA or EPA then the daily amount preferably lies in the range of 0.01 µg (preferably 1.0 µg) to 2.0 g of long-chain poly-unsaturated fatty acid.

Suitable calcium forms are e.g. calcium phosphate, calcium citrate, calcium carbonate or calcium amino acid chelate.

Suitable magnesium forms are e.g. magnesium oxide or magnesium sulfate.

Suitable iron forms are e.g. iron pyrophosphate, iron polymaltose, iron sulphate or iron chelate.

Suitable zinc forms are e.g. zinc sulphate or zinc lactate.

Suitable copper forms are e.g. copper gluconate, copper sulphate or copper oxide.

Suitable iodine forms are e.g. potassium iodide or potassium iodate.

Preferably the nutritional composition further comprises one or more of the following minerals and vitamins: potassium, selenium, manganese, vitamin K, biotin, pantothenic acid, choline, vitamin D3 and beta-carotene. Typical daily amounts of these minerals and vitamins are 0.1 mg to 5 g of potassium, 0.1 µg to 200 µg of selenium, 0.1 µg to 500 µg manganese, 0.1 µg to 200 µg vitamin K, 0.1 µg to 150 µg biotin, 0.1 µg to 5 mg pantothenic acid, 0.1 mg to 1 g choline, 0.1 µg to 30 µg of vitamin D3 and 0.1 mg to 30 mg of beta-carotene.

Suitable potassium forms are e.g. potassium citrate or potassium phosphate.

A suitable selenium form is e.g. selenium yeast.

A suitable manganese form is e.g. manganese phosphate.

The nutritional composition preferably further comprises a carbohydrate source. Typically daily amounts of 20 g to 70 g of a carbohydrate source are provided.

Suitable carbohydrate sources include maltodextrins, malt extract, cereals, fruit flakes, invert sugar, sucrose, fructose, dextrose and glucose, whereby maltodextrin and cereals are preferred.

The nutritional composition may be in the form of a soup or drink such as a powdered cold or hot water instant drink or soup or a ready-to-consume liquid form, in the form of a bar such as a cereal or fruit bar, in form of a salted or sweet biscuit or in the form of a meal replacement.

Preferably the composition of the invention provides the daily amounts of essential nutrients in a single dose unit.

The nutritional compositions of the present invention can be formulated into food products or dietary supplements.

Therefore the invention also relates to food products comprising the nutritional composition of the invention. The term "food product" is intended to cover the whole variety of foods and beverages, including but not limited to powdered instant drinks, baked products such as bread, crisp bread, crisp bread sandwiches, biscuits and cakes, dairy substitute foods, desserts, confectionary products, spreads, cereal and/or fruit bars, breakfast cereals, juices and the like. Preferred food formats are powdered instant drinks and cereal bars.

Preferred as food products are those which are likely to be classified as "functional foods", i.e. foods that are similar in appearance to conventional foods and are intended to be consumed as part of a normal diet or as a supplement, but have been nutritionally tailored to perform physiological roles beyond the provision of simple nutrient requirements.

The invention also foresees dietary supplements comprising the composition of the invention. Typically, the latter are intended for ingestion in pill, capsule, tablet, chewable candies, tabs or liquid form.

Also provided is the use of the composition of the invention in the manufacture of a food product or dietary supplement for pregnant and lactating women.

The invention further provides a method for supplementing the extra-needs of essential nutrients of pregnant and lactating women and for treating and/or preventing constipation comprising administering to said pregnant and lactating women effective amounts of

a nutritional composition comprising:

 a non-milk-derived protein source,
 a dietary fibre and/or fibre-like substance,
 a source of polyunsaturated fatty acids,
 minerals and vitamins recommended for pregnant and lactating women,
whereby the composition is lactose-free and contains less than 2 % of milk or milk-derived products by weight of dry components of the composition.

The invention will be further illustrated by the following examples.

Example 1

A powdered cold water instant drink, to be reconstituted by 35g powder in 150 ml cold water which has following profile: Recommended daily amount 35g

soya isolate	34.0%
sucrose	18.0%
fructo-oligosaccharides	15.6%
encapsulated fish oil, BASF	9.6%
maltodextrin DE20	8.6%
cocoa powder	7.0%
mineral mix	4.0%
chocolate flavour	1.5%
MCT oil	1.0%
vitamin mix	0.4%
vanilla	0.3%

All ingredients are passed through a sieving machine with sieve (mesh size 1.45mm). The MCT oil is added to the maltodextrin and mixed for 10 minutes in a Carpentier mixer. Then the remaining ingredients are added to the maltodextrin blend and further mixed for 20 minutes.

With the following mineral mix (MM) composition:

maltodextrin DE20	54.6865 %
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calcium-tri-phosphate	30.0%
magnesium oxide, light	10.2%
iron pyrophosphate	3.8%
zinc sulfate	1.15%
copper gluconate	0.16%
potassium iodide	0.0035%

All ingredients of the mineral mix are passed through a sieving machine with sieve (mesh size 1.45mm), then mixed in a Ruberg mixer for 15 minutes.

With the following vitamin mix (VM)

maltodextrin DE 20	44.203%
Vitamin C	30%
beta carotene 10%	12.7%
Vitamin E acetate 50%	7.4%
Niacinamide	1.85%
Vitamin D3	1.75%
Vitamin A acetate 325	0.95%
Vitamin B ₂	0.4%
Vitamin B ₆ HCl	0.29%
Folic acid	0.21%
Vitamin B ₁ nitrate	0.2%
Vitamin B ₁₂ 1%	0.047%

All ingredients of the vitamin mix are passed through a sieving machine with sieve (mesh size 1.45mm), then mixed in a Ruberg mixer for 15 minutes.

Example 2

A cereal bar with the following profile: Recommended daily amount 40 g

glucose syrup	25.0 %
invert sugar	8.0 %
oat flakes	16.29%
crisp rice	10.0 %

soya isolate	12.0 %
fructo-oligosaccharides	10.0 %
banana flakes	7.5 %
sunflower oil	7.5 %
MM (as in Example 1)	1.2 %
VM (as in Example 1)	0.5 %
source of microalgae oil DHASCO, Martek Biosciences Corporation	1.5 %
soya lecithin	0.5 %
antioxidant vit E	0.01 %

The glucose syrup and inverted sugar are heated up to 110°C. The sunflower oil is first warmed separately to 50°C in a tank, then the soya lecithin and antioxidant are added to the sunflower oil and mixed until homogenous. The oil blend is added to the syrup mix and mixed in a dough mixer for 10 minutes. The microalgal oil is added and further mixed for 5 minutes. All the remaining ingredients are added and further mixed for 10 minutes. Then the mass is rolled out, cooled down to 20°C and formed into bars.

Example 3

A powdered cold water/juice instant drink, to be reconstituted by 32g powder in 150-200 ml cold water or fruit juice which has following profile: Recommended daily amount 32g

Composition:

pea protein	19.0%
sucrose	32.36%
inulin	13.8%
encapsulated fish oil, BASF	8.6%
maltodextrin DE20	9.6%
banana powder	5.0%
oat fiber	4.0%
calcium lactate, soluble	3.32
banana flavour	1.6%
Mg-glycerophosphate	..0.85%
Ca-H-phosphate	..0.5%

mineral mix	..0.46%
choline-H-tartrate	..0.38%
vitamin mix	..0.26%
xanthan gum	..0.25%
beta-carotene	..0.02%

With the following mineral mix composition:

maltodextrin DE20	48.664 %
iron-III-pyrophosphate	39.46%
selenium yeast 1000	6.5%
zinc sulphate	5.35%
potassium iodide	0.026%

All ingredients of the mineral mix are passed through a sieving machine with sieve (mesh size 1.45mm), then mixed in a Ruberg mixer for 15 minutes.

With the following vitamin mix

maltodextrin DE 20	13.606%
Vitamin C	65%
Vitamin K ₁ powder 5%	0.15%
Vitamin E acetate 50%	8.3%
Niacinamide	2.7%
Vitamin D3	2.8%
Vitamin A acetate 325	4.8%
Vitamin B ₂	0.42%
Vitamin B ₆ HCl	1.5%
Folic acid	0.001%
Vitamin B ₁ nitrate	0.65%
Vitamin B ₁₂ 1%	0.073%

All ingredients of the vitamin mix are passed through a sieving machine with sieve (mesh size 1.45mm), then mixed in a Ruberg mixer for 15 minutes.

Example 4

A liquid product with the following profile: Recommended daily portion 200 ml

water	80.09%
sucrose	7.5%
soya isolate	6.0%
MM (as in Example 1)	1.0%
VM (as in Example 1)	0.5%
fructo-oligosaccharides	3.0%
microalgae oil DHASCO, Martek Biosciences Corporation	1.0%
sodium carbonate	0.2%
vanilla	0.3%
soya lecithin	0.4%
antioxidant vit E	0.01%

Add soya isolate in 50% of water and pass the blend through a colloid mill. Leave the mix for two hours. Add the sucrose, fructo-oligosaccharide and mineral mix in 30% of water and add to the soya isolate blend and heat it up to 65°C in a tank. Add emulsifier and antioxidant to the microalgal oil, mix shortly and add to blend. Add vitamins and vanilla to the blend, homogenize the mix at 170/50 bar and treat under UHT conditions (141°C for 5 sec.). The mix is then cooled down to 20°C, stored in a sterile tank and aseptically filled into brik type packages.

Claims:

1. A nutritional composition for pregnant and lactating women comprising:
 - a non-milk-derived protein source,
 - a dietary fibre and/or fibre-like substance,
 - a source of polyunsaturated fatty acids,
 - minerals and vitamins recommended for pregnant and lactating women,characterized in that the composition is lactose-free and contains less than 2 % of milk or milk-derived products by weight of dry components of the composition.
2. The composition according to claim 1, comprising the following minerals and vitamins: calcium, magnesium, iron, copper, zinc, iodine, vitamin A, vitamin E, vitamin B₁, vitamin B₂, vitamin B₆, vitamin B₁₂, vitamin C, folic acid, niacin.
3. The composition according to claim 1 or claim 2 comprising the following daily amounts of essential nutrients:
 - 1.0 mg (preferably 1.0 g) to 50 g of a non-milk-derived protein source, preferably 8 to 15 g, particularly preferred 10 g,
 - 1.0 mg to 30 g of dietary fibre and/or fibre-like substance, preferably 4 to 6 g, particularly preferred 5 g,
 - of polyunsaturated fatty acids
 - 0.01 µg (preferably 0.1 µg) to 2.0 g of long-chain polyunsaturated fatty acids, preferably 0.1 to 0.4 g, particularly preferred 0.25 g and/or
 - 0.5 g to 12 g of alpha-linolenic acid, preferably 0.5 to 2.0 g, particularly preferred 1.0 g and/or
 - 1 g to 30 g of linoleic acid, preferably 2.0 to 5.0 g, particularly preferred 3.0 g,
 - 0.1 mg to 3.6 g calcium, preferably 320 to 530 mg, particularly preferred 400 mg,
 - 0.1 mg to 1.1 g magnesium, preferably 60 to 90 mg, particularly preferred 75 mg,
 - 0.01 mg to 90 mg iron, preferably 8 to 12 mg, particularly preferred 10 mg,
 - 0.01 mg to 60 mg zinc, preferably 4 to 6 mg, particularly preferred 5 mg,
 - 0.01 mg to 3 mg copper, preferably 0.1 to 0.4 mg, particularly preferred 0.25 mg,
 - 0.01 mg to 0.6 mg iodine, preferably 24 to 36 µg, particularly preferred 30 µg,
 - 0.01 mg to 4.0 mg vitamin A, preferably 80 to 120 µg, particularly preferred 100 µg,

0.01 mg to 40 mg vitamin E, preferably 2.4 to 3.6 mg, particularly preferred 3 mg,
0.01 mg to 5 mg vitamin B₁, preferably 0.16 to 0.24 mg, particularly preferred 0.2 mg,
0.01 mg to 6 mg vitamin B₂, preferably 0.32 to 0.48 mg, particularly preferred 0.4 mg,
0.01 mg to 7 mg vitamin B₆, preferably 0.24 to 0.36 mg, particularly preferred 0.3 mg,
0.01 µg to 8 µg vitamin B₁₂, preferably 0.4 µg to 0.6 µg, particularly preferred 0.5 µg,
0.01 mg to 300 mg vitamin C, preferably 20 to 30 mg, particularly preferred 25 mg,
1.0 µg to 1.2 mg folic acid, preferably 160 to 240 µg, particularly preferred 200 µg,
and
0.01 mg to 60 mg niacin, preferably 1.6 to 2.4 mg, particularly preferred 2 mg.

4. The composition according to any one of the preceding claims further comprising one or more of the following minerals and vitamins: potassium, selenium, manganese, vitamin K, biotin, pantothenic acid, choline, vitamin D3 and beta-carotene.
5. The composition according to any one of the preceding claims wherein the non-milk derived protein source is selected from one or more members of the group consisting of egg protein, soy protein (particularly soy protein low in isoflavones), soy isolate, pea protein, pea hydrolysate, rice protein, rice hydrolysate, soy hydrolysate, wheat hydrolysate, potato hydrolysate, rapeseed protein, lupin protein, wheat protein and wheat isolate.
6. The composition according to any one of the preceding claims, wherein the fibre-like is an oligosaccharide, in particular a fructo-oligosaccharide and/or a xylo-oligosaccharide.
7. The composition according to any one of the preceding claims wherein the daily amounts of essential nutrients are provided for in a single dose unit.
8. A food product or dietary supplement comprising the composition according to any one of the preceding claims.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A23L1/308 A23L1/30 A23L1/305

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A23L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 737 364 A (KALOGRIS THEODORE P) 12 April 1988 (1988-04-12) column 3, line 5 - line 24; example 1 ---	1-8
X	H. SCHERZ, F. SENSER: "Food Composition and Nutrition Tables 1989/90" 1989, WISSENSCHAFTLICHE VERLAGSGESELLSCHAFT MBH, STUTTGART XP002114112 pages 679, 680, 702-705, 708, 709, 808, 809 --- -/-	1-8

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Patent family members are listed in annex.

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NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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